#### Remarks

#### Introduction

Claims 1-19 were pending. By way of this response, claims 1, 7, 8, and 16 have been amended, and claim 17 has been cancelled without prejudice. Claims 1, 7, 8, and 16 have been amended to include subject matter of claim 17. Support for the amendments to the claims can be found in the specification as filed, and care has been taken to avoid adding new matter. For example, support for the amendments to the claims can be found at page 11, lines 16-18. Accordingly, claims 1-16, 18, and 19 are currently pending.

# Rejections Under 35 U.S.C. § 112, first paragraph

Claims 1-16 and 19 have been rejected under 35 U.S.C. § 112, first paragraph as allegedly failing to comply with the written description requirement.

Applicant does not concede with the rejections or remarks made by the Examiner. However, to advance the prosecution of the above-identified application, independent claims 1, 7, 8, and 16 have been amended by deleting the phrase "at a location inferior to the nose of the patient" and by inserting subject matter of claim 17, which was not rejected under 35 U.S.C. § 112, first paragraph.

In view of the above, applicant submits that the present claims 1-16, 18, and 19, satisfy of 35 U.S.C. requirements S 112, first paragraph, and

respectfully requests that the rejection of the present claims based on this statutory provision be withdrawn.

# Rejections Under 35 U.S.C. § 112, second paragraph

Claims 1-16 and 19 have been rejected under 35 U.S.C. § 112, second paragraph as allegedly being indefinite.

Applicant does not concede with the rejections or remarks made by the Examiner. However, to advance the prosecution of the above-identified application, independent claims 1, 7, 8, and 16 have been amended by deleting the phrase "at a location inferior to the nose of the patient" and by inserting subject matter of claim 17, which was not rejected under 35 U.S.C. § 112, second paragraph.

In view of the above, applicant submits that the present claims 1-16, 18, and 19, that is claims. 35 U.S.C. S 112, second paragraph, and of requirements respectfully requests that the rejection of the present claims based on this statutory provision be withdrawn.

## Rejections Under 35 U.S.C. § 102

Claims 1-17 and 19 have been rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Sanders and Quinn (WO 00/10598.

Applicant traverses the rejection as it relates to the presently amended claims.

botulinum that recite а 1 and 7 Claims administered to a region of a patient selected from the group consisting of the gastrointestinal tract and the genital tract. Claims 8 recites that a botulinum toxin is administered to a mucus secreting gland of a region selected from the group consisting of the gastrointestinal tract, the genital tract, and the respiratory tract of a patient. Claim 16 recites injecting an excessively secreting, cholinergic nervous system influenced mucus gland or local gland area of a region selected from the group consisting of the gastrointestinal tract, the genital tract, and the respiratory tract of a patient.

Applicant submits that Sanders does not disclose, teach, or For example, Sanders does not suggest the present invention. disclose, teach, or even suggest administration of a botulinum to a region of a patient selected from the group consisting of the gastrointestinal tract and the genital tract, Similarly, Sanders does not as recited in claims 1 and 7. disclose, teach, or even suggest administering a botulinum toxin to a mucus secreting gland of a region selected from the group consisting of the gastrointestinal tract, the genital tract, and the respiratory tract of a patient, as recited in claim 8. Sanders also does not disclose, teach, or even suggest injecting an excessively secreting, cholinergic nervous system influenced mucus gland or local gland area of a region selected from the group consisting of the gastrointestinal tract, the genital tract, and the respiratory tract of a patient, as recited in claim 16.

As acknowledged by the Examiner, Sanders discloses administration of a botulinum toxin to bronchial muscles to

relax the bronchial muscles (see Office Action, page 5, first paragraph).

Independent claims 1 and 7 recite administering a botulinum toxin to a region of the gastrointestinal tract or genital tract. Sanders fails to disclose, teach, or even suggest any administration of a botulinum toxin to the gastrointestinal tract or genital tract.

Independent claims 8 and 16 recite administring a botulinum toxin to a mucus secreting gland (claim 8) or to an excessively secreting, cholinergic nervous system influenced mucus gland or local mucus gland area (claim 16) of a region selected from the group consisting of the gastrointestinal tract, the genital tract, and the respiratory tract. Similar to claims 1 and 7, Sanders does not disclose, teach, or even suggest administration of a botulinum toxin to the gastrointestinal tract or genital tract, let alone to a mucus secreting gland or to an excessively secreting, cholinergic nervous system influenced mucus gland or local mucus gland area of the gastrointestinal tract or genital tract of a patient. Furthermore, Sanders does not disclose, teach, or even suggest administration of a botulinum toxin to a secreting gland or to an excessively mucus cholinergic nervous system influenced mucus gland or local mucus gland area of the respiratory tract.

As discussed above, Sanders only discloses administration of a botulinum toxin to bronchial muscles in asthmatic or COPD patients (Example VIII of Sanders). Applicant submits that mucus is not secreted from muscle cells. Therefore, Sanders

does not disclose, teach, or even suggest the subject matter of claims 8 and 16.

In view of the above, applicant submits that the present claims, that is claims 1-16, 18, and 19, are not anticipated by Sanders and Quinn under 35 U.S.C. § 102.

In addition, each of the present dependent claims is separately patentable over the prior art. For example, none of the prior art disclose, teach, or even suggest the present methods including the additional feature or features recited in any of the present dependent claims. Therefore, applicant submits that each of the present claims is separately patentable over the prior art.

## Conclusion

In conclusion, applicant has shown that the present claims satisfy the requirements of 35 U.S.C. § 112, first and second paragraph, and are not anticipated by the prior art under 35 Therefore, applicant submits that the present U.S.C. § 102. and 19, are allowable. claims 18, 1-16, claims, that is Therefore, applicant respectfully requests the Examiner to pass the above-identified application to issuance at an early date. Should any matters remain unresolved, the Examiner is requested to call (collect) applicant's attorney at the telephone number given below.

Date: 5/25/05

Respectfully submitted,

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